93-1116

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In The
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1993

In Re: WILLIAM FALOON and
SAUL KENT, Petitioners,
v.
UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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QUESTION PRESENTED

Whether the Eleventh Circuit utilized an incorrect legal standard in deciding against allowing limited testimony of FDA Commissioner David Kessler in a federal criminal case involving selective prosecution issues where the trial court was conducting an evidentiary hearing and permitted such discovery, and where Commissioner Kessler was a fact witness who had personal contacts with individuals similarly situated to the defendants below?

CERTIFICATE OF INTERESTED PERSONS

Petitioners, William Faloon and Saul Kent, submit the following list of interested persons.

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William Faloon

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The Honorable Jose A. Gonzalez, Jr.,
U.S. District Court Judge

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The Honorable Lurana S. Snow, U.S. District Court Magistrate

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PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Petitioners Saul Kent and William Faloon, defendants and respondents in the courts below, respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit entered in this case on February 23, 1993.

OPINIONS BELOW

The Opinion of the Court of Appeals for the Eleventh Circuit is reported as follows: In Re: United States of America, 985 F.2d 510 (11th Cir. 1993). A copy of the Opinion is attached in the Appendix hereto (hereinafter "Pet. App." at 1.). The unpublished Order denying the Petition for Rehearing was entered on April 15, 1993. See Pet. App. at 13.

JURISDICTION

The judgment of the United States Court of Appeals for the Eleventh Circuit was entered on February 23, 1993. See Pet. App. at 1. A timely Petition for Rehearing was filed, which the Eleventh Circuit denied on April 15, 1993. See Pet. App. at 13. The jurisdiction of this Court to review the judgment of the Eleventh Circuit is conferred under 28 U.S.C. Section 1254(1).

STATEMENT OF THE CASE

Petitioners, Saul Kent and William Faloon, have for years been vocal and vociferous critics of the FDA and proponents of freedom of choice in health care. In November 1991, Petitioners were indicted in connection with allegedly helping American consumers import from abroad small quantities of unapproved medications for personal use consumption. Because the FDA so rarely seeks criminal prosecution for violations of the Food and Drug Act; because numerous companies

and individuals similarly situated to Petitioners have gone unprosecuted; because Petitioners' conduct appeared consistent with the FDA mail import policy; because of the de minimis nature of Petitioners' alleged activities; and because the instant prosecution on its face appears motivated by a FDA initiative to chill Petitioners' First Amendment Rights, Petitioners filed a motion to dismiss on grounds of selective prosecution in March of 1992.

On March 30, 1992, Petitioners filed a Motion seeking discovery and an evidentiary hearing on their selective prosecution motion. United States Magistrate Lurana S. Snow made a finding at a hearing in April of 1992, that Kent and Faloon, in their motion to dismiss, stated a colorable basis for their selective prosecution claim and ordered the Respondent/Government to produce records and

scheduled an evidentiary hearing.[1] Magistrate Snow conducted an evidentiary hearing on the selective prosecution issues over a several month period, including hearing days on July 21, 1992; December 17, 1992; and February 9-10, 1993. Petitioners subpoenaed FDA Commissioner David Kessler in July, 1992, to testify at the July hearing regarding personal contacts Commissioner Kessler had with individuals engaged in comparable conduct to what is alleged against Kent and Faloon.

Petitioners agreed to first take testimony from other FDA officials in hopes of obviating the need to question Kessler. Accordingly, Petitioners permitted the government to produce FDA employees Daniel Michels and Randolph Wykoff in lieu of Kessler at the July and December, 1992 hearings respectively. Michels and Wykoff, however, were not able to answer questions regarding

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[1]Respondent never "appealed" this finding to United States District Judge Jose A. Gonzalez and such finding is not at issue herein.

Kessler's firsthand involvement with others similarly situated to Petitioners. Therefore, Petitioners scheduled Kessler to appear at the final hearing in February, 1993.

The government moved to quash Kessler's subpoena in a fifteen-page pleading on January 21, 1993. Petitioners responded to the merits of the motion on January 25, 1993, and offered to take Kessler's testimony by telephone so as to minimize any travel and otherwise make it more convenient for him. On February 2, 1993, Magistrate Snow entered an Order denying the government's motion to quash and holding that Kessler should give testimony by telephone for thirty minutes anytime on February 9, 1993. Judge Gonzalez affirmed Magistrate Snow's Order on February 11, 1993.

On February 10, 1993, Respondent filed an emergency petition for writ of mandamus with the Eleventh Circuit Court of Appeals, attempting to prevent Kessler's telephonic testimony. Petitioners responded to the

government's mandamus petition stating that they sought testimony from Kessler relating to his personal contacts with persons involved in Aids Buyers' Clubs and Kessler's treatment of such persons. Specifically, Petitioners were most interested in Kessler's testimony regarding conversations he has had with Martin Delaney and Jim Corti. Delaney and Corti have for years been engaged in, and continue to engage in, the commercial importation into the United States and sale of huge quantities of new and unapproved drugs, apparently with the specific blessing of Kessler.[2] Kessler himself reportedly stated to Delaney that he was "worried about claims of selective prosecution." See J. Kwitny, Acceptable Risks (Poseidon Press) at p. 391, (a copy of page 391 was attached as an exhibit to the

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[2]Petitioners also stated to the Eleventh Circuit that Aids Buyers' Clubs are similarly situated to Petitioners and that the activities of the Buyers' Clubs parallel the alleged activities of Petitioners. In fact, the conduct at issue in the indictment is less severe than what certain Aids Buyers' Clubs are doing, and, unlike the Buyers' Clubs, in accordance with the FDA's mail import policy.

materials submitted by Petitioners to the Eleventh Circuit).

The Eleventh Circuit entered an Opinion on February 23, 1993, reversing the trial court and directing the trial court to quash the subpoena of Kessler. See In Re: United States of America, 985 F.2d 510 (11th Cir. 1993). The Eleventh Circuit denied Petitioners' petition for rehearing on April 15, 1993. See Pet. App. at 13. Petitioners' selective prosecution motion remains pending before the trial court.

REASONS FOR GRANTING THE WRIT

I. DEFENDANTS IN A CRIMINAL CASE ARE ENTITLED TO ELICIT BRIEF TESTIMONY OF AN AGENCY HEAD WHERE THE TRIAL COURT PERMITTED DISCOVERY AND AN EVIDENTIARY HEARING INVOLVING SELECTIVE PROSECUTION ISSUES, AND WHERE THE AGENCY HEAD IS A CRITICAL FACT WITNESS REGARDING HIS PERSONAL CONTACTS WITH INDIVIDUALS SIMILARLY SITUATED TO THE DEFENDANTS AND THE ELEVENTH CIRCUIT UTILIZED AN INCORRECT LEGAL STANDARD IN RESOLVING THIS ISSUE BELOW

A. The Right to Elicit Firsthand Factual Testimony Is Particularly Strong In A Criminal Case

In ruling against Petitioners, the Eleventh Circuit completely overlooked a defendant's important discovery rights in a criminal case. The Court's opinion does not even mention the criminal discovery standards in its analysis of the issues here. The general standards regarding a defendant's discovery rights in criminal cases are well-settled. See e.g., Will v. United States, 389 U.S. 90 (1967); United States v. Nixon, 418 U.S. 683 (1974); In Re: Martin Marietta Corp., 856 F.2d 619 (4th Cir.), cert. denied, 490 U.S. 1011 (1989); United States v. McGrady, 508 F.2d 13 (8th Cir.), cert. denied, 420 U.S. 979 (1975); United States v. Poindexter, 727 F.Supp 1501 (D.D.C. 1989), 732 F.Supp. 135 (D.D.C. 1990); United States v. Myerson, 684 F.Supp 41 (S.D.N.Y. 1988). Most of the reported cases involve duces tecum subpoenas. The standard for whether a duces tecum subpoena should be quashed in a criminal case is generally whether: (1) the documents at

issue are evidentiary; (2) the documents are not otherwise procurable; (3) the party seeking the documents cannot properly prepare for trial without such documents in advance of trial; and (4) the application is made in good faith and is not intended as a general "fishing expedition." See Nixon 418 U.S. at 700-01.

In this case, as the Magistrate and trial Judge found, Petitioners easily met these requirements.[3] The trial Court specifically found that Petitioners stated a colorable basis for their selective prosecution claim and ordered discovery and granted an evidentiary hearing. Kessler is a fact witness who alone possesses information

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[3]In addition, Petitioners submit that the Eleventh circuit misapplied the standards of mandamus in criminal cases and erred in its ruling that mandamus as opposed to the entry of a criminal contempt order and review therefrom is the appropriate remedy herein. See, e.g., Will v. United States, 389 U.S. 90, 96-98 (1967); (judicial caution traditionally associated with mandamus must be heightened in criminal cases). Petitioners do not seek a writ of certiorari on this issue because regardless of what procedural route ultimately led to appellate review, the reviewing court has already erroneously ruled on the merits of the Kessler subpoena.

germane to the selective prosecution inquiry. This information is not otherwise procurable. The testimony is especially important given the heightened burden respondents have in proving their selective prosecution claim. Petitioners simply cannot fairly and adequately prosecute their claim without this testimony. Moreover, the Kessler subpoena was issued in good faith and in no way intended to produce any fishing expedition into FDA policies.

B. **Why Kessler's Testimony Was Sought**

FDA Commissioner David Kessler's testimony goes to the heart of Petitioners' claim of selective prosecution. Kessler has himself had conversations with Martin Delaney and Jim Corti, persons who have for years been engaged in, and continue to engage in, the importation into the United States and sale of huge quantities of new and unapproved drugs, apparently with the specific blessing of

Kessler. Delaney and Corti's conduct with Aids Buyers' Clubs parallel the activities of Petitioners and in many ways, the conduct of the Buyers' Clubs is even more egregious than what the government alleges Petitioners have engaged in.

Kessler himself reportedly stated to Delaney that he was "worried about claims of selective prosecution." See J. Kwitny, Acceptable Risks (Poseidon Press) at p. 391. Kessler, if his subpoena were not quashed, would explain a course of conduct where he has knowingly and selectively favored a group of individuals doing comparable things to what is alleged against Petitioners. Moreover, not only has Kessler apparently agreed not to prosecute Delaney, Corti and others associated with Aids Buyers' Clubs, Kessler has openly permitted them to import and sell large quantities of unapproved new drugs for commercial purposes without commencing any enforcement action, let alone criminal

prosecution. Petitioners simply cannot fairly and adequately prosecute their selective prosecution claim without Kessler's testimony, which on these issues is clearly relevant, admissible and material; is non-cumulative; and is not otherwise procurable.

Indeed, by not permitting Petitioners to elicit testimony from Kessler as to issues of which only he in the FDA has firsthand knowledge, the Eleventh Circuit has in essence imposed a near blanket prohibition against testimony from agency heads in criminal cases.

C. The Eleventh Circuit Applied the Wrong Standard

The Eleventh Circuit misapprehended the issue in concluding Petitioners have not shown a special need to elicit the testimony of Mr. Kessler. The Eleventh Circuit's reasons for barring the testimony were that 1) alternative witnesses were available to Petitioners at the selective prosecution hearing, and 2) Mr. Kessler was not in charge

of the FDA at the time Petitioners were initially investigated by the FDA and when this case was referred to the Justice Department for criminal prosecution. See Pet. App. at p. 10-11. Although these two statements are technically correct, such facts miss the point as to why Mr. Kessler was subpoenaed.

The FDA witnesses produced by the government in lieu of Mr. Kessler at prior hearing days, including Daniel Michels and Randolph Wykoff, were simply not able to answer questions regarding Mr. Kessler's firsthand involvement with Martin Delaney and Jim Corti and others involved with Aids Buyers' Clubs. Moreover, Petitioners subpoenaed Delaney, Corti and others involved with Aids Buyers' Clubs and they either declined to appear or declined to testify by asserting the Fifth Amendment privilege. While the FDA made witnesses available to Petitioners in lieu of Mr. Kessler, since

these witnesses had no knowledge of facts relating to Mr. Kessler's meetings, conversations and personal policy decisions regarding persons importing large quantities of unapproved drugs, Petitioners have no way, other than by questioning Mr. Kessler, to develop evidence at the motion hearing of Mr. Kessler's dealings with Corti and Delaney.

Petitioners concede that Mr. Kessler was not in charge of the FDA at the time this case originated within the FDA. Mr. Kessler became Commissioner of the FDA, however, in November 1990, which is a year before Petitioners were indicted in November 1991. Moreover, Mr. Kessler, as the current head of the FDA, is responsible for the ongoing enforcement of the Food, Drug and Cosmetic Act. Evidence that he has personally permitted some individuals for years to engage in, and continue to engage in, the importation into the United States of large quantities of unapproved new drugs for commercial purposes without commencing any

enforcement action, let alone criminal prosecution goes to the heart of the selective prosecution issue. The fact that Mr. Kessler was not Commissioner before November 1990, is, therefore, irrelevant.

By requiring Petitioners to show special need and by concluding special need had not been shown, the Eleventh Circuit erred. Such an approach toward agency heads simply does not work in the context of criminal prosecutions and misapplies the analysis approved in United States v. Nixon, supra, and its progeny.

D. **Policy Considerations**

This case raises serious issues brought together by the clash of important discovery rights in criminal cases and the general need to protect agency heads from overly burdensome testimony. In particular, this case requires a balancing of the rights of criminal defendants who have demonstrated colorable claims in a selective prosecution

case involving the FDA with the FDA Commissioner's desire to be free of the burden of providing testimony. What has happened in this case is that the Eleventh Circuit has misapprehended why Petitioners sought Kessler's testimony; what Petitioners sought from him; and what standard to use to decide the issue.

The Eleventh Circuit's decision is dangerously akin to holding that criminal defendants may never obtain the testimony of agency heads or high government officials. It imposes an unfair burden on defendants to establish some nebulous "special need." Without seeking to overstate the precedent which has now been set or to overdramatize its impact, we submit that a court could, for example, based on the Eleventh Circuit's opinion below, wrongly deny a defendant charged with murder the ability to seek the testimony of a high government official who was an eye witness to the murder. In fact, a

court could arguably deny a defendant such testimony even if it would exculpate the defendant. The Eleventh Circuit's opinion is already well on its way down this dangerous and slippery slope. This Court should, therefore, grant certiorari so that it can clarify the standards that apply when testimony is sought in criminal cases from agency heads.

CONCLUSION

For all of the foregoing reasons, Petitioners respectfully ask the Court to grant this Petition for Certiorari. Alternatively, this Court should grant certiorari, vacate the judgment below and immediately remand this case with instructions that the Eleventh Circuit require the trial court to conduct a hearing as to the extent of Petitioners' need to elicit the testimony of Commissioner Kessler.

Respectfully submitted,

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I hereby certify that on July 12th, 1993, a copy of the foregoing was mailed to:

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GUY A. RASCO, ESQ.

APPENDIX

985 Federal Reporter, 2d Series

In re UNITED STATES of AMERICA Petitioner

No. 93-4147.

United States Court of Appeals, Eleventh Circuit.

February 23, 1993.

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Michael S. Pasano, Zuckerman, Spaeder, Taylor & Evans, Miami, FL, for Kent.

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On Petition for Writ of Mandamus to the United States District Court for the Southern District of Florida.

Before KRAVITCH, ANDERSON and DUBINA, Circuit Judges.

PER CURIAM:

Before us is the government's emergency petition for a writ of mandamus requesting that we quash a subpoena for a witness in the

case of United States of America v. Faloon, No. 91-0221 (S.D.Fla. filed Nov. 2, 1991). Defendants William Faloon and Saul Kent were indicted for introducing unapproved drugs, misbranded drug products and misbranded prescription drugs into interstate commerce in violation of 21 U.S.C. §§333(a)(2), 353(b)(1), 331(a), 333(b) and 18 U.S.C. §542. Pending before the district court is the defendants' motion to dismiss the indictment on the ground of selective prosecution. The defendants claim that the Food and Drug Administration (FDA) has failed to prosecute others similarly situated, specifically groups which have imported and distributed drugs not yet approved by the FDA. To substantiate this claim, defendants subpoenaed Dr. David Kessler, Commissioner of the FDA.

The magistrate denied the government's motion to quash the subpoena, ruling that Dr. Kessler may testify by telephone and is required to be available for thirty minutes.

The district court denied the government's appeal of the magistrate's order. The government then filed a motion asking this court to issue a mandamus order compelling the district court to quash the subpoena. Pursuant to a request from this court, defendants filed a response to the government's motion.

[1,2] We recognize that mandamus is an extraordinary remedy and will not lie if other remedies are available. See In re Fink, 876 F.2d 84 (11th Cir. 1989); U.S. v. Denson, 603 F.2d 1143 (5th Cir. 1979); Huckeby v. Frozen Food Exp., 555 F.2d 542 (5th Cir. 1977).[1] Generally, an appellate court will not order a district court to quash a subpoena for a witness to testify as the witness can appeal a contempt citation if he or she fails to respond to the subpoena. As a rule, this

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[1]The Eleventh Circuit, in an en banc decision, Bonner v. City of Pritchard, 661 F.2d 1206, 1209 (11th Cir. 1981), adopted as precedent decisions of the former Fifth Circuit rendered prior to October 1, 1981.

occurs in the context of grand jury testimony. See United States v. Ryan, 402 U.S. 530, 533, 91 S.Ct. 1580, 1581-82, 29 L.Ed.2d 85 (1971); In re Fine, 641 F.2d 199, 201 (5th Cir. Unit A 1981).

An exception, however, has been recognized if the witness is a high government official. In United States v. Nixon, 418 U.S. 683, 94 S.Ct. 3090, 41 L.Ed.2d 1039 (1974), the Supreme Court found an exception when the President has been subpoenaed. The Court reasoned that to force the President to incur a contempt order would be unseemly and would cause an unnecessary confrontation between two coequal branches of the government. In addition, the issue of whether the President can be cited for contempt would have to be litigated, incurring further delay in reaching the underlying claims. Id. at 691-92, 94 S.Ct. at 3099. Due to these considerations, the Court held that the issue was properly

before the Court of Appeals without a contempt order.

At least two circuits have acknowledged that some of the Nixon factors can be relevant in cases of high officials who do not have the President's status. In a case involving a contempt citation against the Attorney General, the Second Circuit held that although the Nixon rule did not apply to an official without the executive responsibilities of the President, the court had jurisdiction to issue the writ of mandamus because a contempt sanction "raised separation of powers overtones, and warranted more sensitive judicial scrutiny than such a sanction imposed on an ordinary litigant." In Re Attorney General, 596 F.2d 58, 64 (2d Cir. 1979). In United States v. Winner, 641 F.2d 825 (10th Cir. 1981), the Tenth Circuit noted that the positions of the subpoenaed witnesses, the Deputy Attorney General and Assistant Attorney General, did not bring them within the rule

stated in Nixon; however, they were "high level public officials of a coequal branch of government exercising power entrusted to them by both the legislative and executive departments." Id. at 830. This factor, as well as the important interests and issues presented, merited invocation of the Winner court's jurisdiction to issue a mandamus order. Id.

[3] Similarly, this case involves a high level official who does not come within the Nixon exemption per se, but who is the head of an important executive agency charged with ensuring the health and safety of the public. Requiring the FDA Commissioner to fight the subpoena by placing himself in contempt implicates separation of powers concerns and would harm the public perception of the FDA. The Commissioner would have to take valuable time away from other tasks in deciding whether to incur the sanction of the court. In addition, requiring the Commissioner to

disobey an order of the court would prolong the litigation of this tangential issue and delay the trial of the underlying criminal offense. Because of the importance of the issue presented and the serious implications of forcing the FDA Commissioner to incur a contempt sanction before granting review, we hold that a writ of mandamus, if warranted, is the appropriate remedy.

As to the merits of this mandamus claim, the Supreme Court has indicated that the practice of calling high officials as witnesses should be discouraged. See United States v. Morgan, 313 U.S. 409, 61 S.Ct. 999, 85 L.Ed 1429 (1941). In Morgan, the Court stated that in an effort to preserve the integrity of the administrative process, the Secretary of Labor should not have been asked to testify. Id. at 422, 61 S.Ct. at 1003-04.

The D.C. Circuit relied on Morgan for its holding that "top executive department officials should not, absent extraordinary

circumstances, be called to testify regarding their reasons for taking official actions." Simplex Time Recorder Co. v. Secretary of Labor, 766 F.2d 575, 586 (D.C. Cir. 1985). The Fifth Circuit recently agreed with the holding in Simplex and cautioned a district court to "remain mindful of the fact that exceptional circumstances must exist before the involuntary depositions of high agency officials are permitted." In Re Office of Inspector General, 933 F.2d 276, 278 (5th Cir. 1991). See also Sweeney v. Bond, 669 F.2d 542, 546 (8th Cir.), cert. denied, 459 U.S. 878, 103 S.Ct. 174, 74 L.Ed.2d 143 (1982) (governor not required to testify absent compelling need); United States v. Merhige, 487 F.2d 25, 29 (4th Cir.), cert. denied, 417 U.S. 918, 94 S.Ct. 2625, 41 L.Ed.2d 224 (1974) (members of Parole Board should be subject to deposition only under "exceptional circumstances"); Peoples v. United States Dep't of Agriculture, 427 F.2d 561, 567 (D.C.

Cir. 1970) (compelling testimony from a cabinet officer "is not normally countenanced").

[4] The reason for requiring exigency before allowing the testimony of high officials is obvious. High ranking government officials have greater duties and time constraints than other witnesses. In this case, the government notes that Commissioner Kessler is responsible for the regulation of all drugs, foods, cosmetics and medical devices as well as overseeing the enforcement of statutes and regulations governing the distribution and sales of these items. Thus, his time is very valuable. This concern about a high official's time constraints is particularly relevant to selective prosecution claims. If the Commissioner was asked to testify in every case which the FDA prosecuted, his time would be monopolized by

preparing and testifying in such cases.[2] In order to protect officials from the constant distraction of testifying in lawsuits, courts have required that defendants show a special need or situation compelling such testimony. See Sweeney, 669 F.2d at 546.

This case does not present extraordinary circumstances or a special need for the Commissioner's testimony; on the contrary, the facts weigh against allowing the subpoena. The record discloses that testimony was available from alternate witnesses, including Daniel L. Michels, the former Director of the FDA's Office of Compliance, and Dr. Randolph Wykoff, Director of the FDA's Office of AIDS Coordination. Both of these officials testified at the hearing on the motion to dismiss the prosecution. Furthermore, Dr.

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[2]Although the magistrate's order allowed the Commissioner's testimony to be taken over the telephone and limited it to a thirty minute period, the cumulative effect of such decisions in all of the cases that the FDA prosecuted would be considerable. Also, the Commissioner would have to spend a significant amount of time preparing for the testimony.

Kessler was not the Commissioner at the time the defendants' case was investigated by the FDA and referred to the Justice Department for prosecution. Dr. Kessler did not assume office until four years after the initial investigation and over two years after the case was sent to the Justice Department for further action; accordingly, he could not have been responsible for selectively prosecuting the defendants.

Requiring Dr. Kessler to incur a contempt sanction would have serious repercussions for the relationship between two coequal branches of government and the public confidence in the FDA. Therefore, we have granted review in this mandamus action. Because of the time constraints and multiple responsibilities of high officials, courts discourage parties from calling them as witnesses and require exigent circumstances to justify a request for their testimony. Defendants have failed to show that such circumstances exist in this case.

Accordingly, the writ of mandamus is GRANTED and the district court is ordered to quash the subpoena of Dr. David Kessler.

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 93-4147

IN RE: UNITED STATES OF AMERICA,

Petitioner,

On Petition for Writ of Mandamus to
United States District Court for the
Southern District of Florida

ON PETITION FOR REHEARING

BEFORE: KRAVITCH, ANDERSON and DUBINA, Circuit Judges.

PER CURIAM:

The petition for rehearing filed by Respondents William Faloon and Saul Kent is denied.

ENTERED FOR THE COURT:

/s/ Phyllis Kravitch
United States Circuit Judge

(2)

No. 93-116

FILED
OCT 27 1993
OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1993

WILLIAM FALOON AND SAUL KENT, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly held that the Commissioner of the Food and Drug Administration should not be required to testify in district court with regard to petitioners' claims of selective prosecution.

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In the Supreme Court of the United States

OCTOBER TERM, 1993

No. 93-116

WILLIAM FALOON AND SAUL KENT, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-12) is reported at 985 F.2d 510. The orders of the district court and the magistrate judge are unpublished.

JURISDICTION

The judgment of the court of appeals was entered on February 23, 1993. A petition for rehearing was denied on April 15, 1993. Pet. App. 13. The petition for a writ of certiorari was filed on July 13, 1993. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This petition arises out of a criminal prosecution brought against petitioners for violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* The Food and Drug Administration (FDA) began an investigation of petitioners in 1986 and referred the case to the Justice Department in 1988. On November 5, 1991, a federal grand jury in Ft. Lauderdale, Florida, returned a 28-count indictment charging petitioners with, *inter alia*, causing unapproved new drugs and misbranded prescription drugs to be introduced into interstate commerce with intent to defraud and mislead, and unlawfully attempting to import prescription drugs through the use of false statements. Pet. App. 2; Gov't C.A. Br. 1-2.

In March 1992, petitioners filed a motion to dismiss the indictment, alleging selective prosecution by the government. Petitioners claimed that the FDA had impermissibly exercised its enforcement discretion in determining when it would proceed against importers of unlawful unapproved drugs. Specifically, petitioners alleged that the FDA has not brought enforcement actions against so-called "AIDS Buyers Clubs," which import AIDS-related drugs for the personal use of AIDS victims. Pet. 3-4; Pet. App. 2; Gov't C.A. Br. 2.

In connection with their motion, petitioners subpoenaed Dr. David Kessler, Commissioner of Food and Drugs, in July 1992. The government filed a motion to quash the subpoena, arguing that Commissioner Kessler had had no involvement with the agency's decisionmaking process in referring petitioners' case to the Justice Department. Indeed, Commissioner Kessler did not assume his duties at

the FDA until December 1990, more than two years after the case had been referred to the Justice Department for prosecution and more than four years after the investigation into petitioners' activities had been initiated. Pet. 5; Pet. App. 11; Gov't C.A. Br. 2-3.

The issue of Commissioner Kessler's testimony was not immediately resolved, because the government made available other FDA officials to testify about the agency's enforcement policy. Those officials included Daniel L. Michels, the former Director of the FDA's Office of Drug Compliance, who testified regarding the FDA's enforcement practices, and Dr. Randolph Wykoff, Director of the FDA's Office of AIDS Coordination, who testified concerning the FDA's policies regarding AIDS Buyers' Clubs. After those witnesses had testified, however, petitioners again sought the Commissioner's testimony concerning the FDA's enforcement policy and subpoenaed him to testify on February 9, 1993. Pet. 5-6; Pet. App. 10; Gov't C.A. Br. 3-4.

2. On February 2, 1993, the magistrate judge denied the government's motion to quash the subpoena of Commissioner Kessler and ordered the Commissioner to present testimony for 30 minutes by telephone. The district court rejected the government's appeal. Pet. 6; Pet. App. 2-3.

3. The court of appeals granted the government's petition for a writ of mandamus and ordered the district court to quash the subpoena of Commissioner Kessler. Pet. App. 1-12. Recognizing the general policy disfavoring compelled testimony of high government officials absent extraordinary circumstances (*id.* at 7-10), the court found that no such circumstances existed in this case. The court ex-

plained that the FDA had provided other witnesses regarding its enforcement policy and that Dr. Kessler did not assume office until over two years after the case had been sent to the Justice Department for prosecution, and thus he "could not have been responsible for selectively prosecuting [petitioners]." *Id.* at 10-11.[1]

ARGUMENT

1. This Court has long held that, absent unusual circumstances, courts should refrain from probing the thought processes of agency decisionmakers. *United States* v. *Morgan*, 313 U.S. 409, 422 (1941). Accordingly, the courts of appeals have consistently recognized that agency heads "should not, absent extraordinary circumstances, be called to testify regarding their reasons for taking official actions." *In re Office of Inspector General*, 933 F.2d 276, 278 (5th Cir. 1991) (quoting *Simplex Time Recorder Co.* v. *Secretary of Labor*, 766 F.2d 575, 586 (D.C. Cir. 1985)). Accord *Peoples* v. *United States Dep't of Agriculture*, 427 F.2d 561, 567 (D.C. Cir. 1970) ("subjecting a cabinet officer to oral deposition is not normally countenanced"); *United States Board of Parole* v. *Merhige*, 487 F.2d 25 (4th Cir. 1973) (Parole Board members could not be deposed absent exceptional circumstances), cert. denied, 417 U.S. 918 (1974); *Warren Bank* v. *Camp*, 396 F.2d 52, 56-57 (6th Cir. 1968) (Comptroller of the Currency could not be

[1] The court of appeals also held that the district court's order compelling the testimony of Commissioner Kessler was reviewable by way of petition for writ of mandamus. Pet. App. 3-7. Petitioners do not seek review of that holding. See Pet. 10 n.3.

deposed absent showing of misconduct); *United States* v. *Winner*, 641 F.2d 825, 834 (10th Cir. 1981) (order compelling testimony of Assistant Attorney General "must be supported by detailed written findings").

The reasons for that rule are self-evident. Agency heads are charged with sweeping statutory responsibilities in furtherance of the public interest. At the same time, their agencies are generally involved in litigation in courts across the Nation. That is particularly true for an agency such as the FDA, which is charged with important and wide-ranging duties, including both civil and criminal law enforcement.[2] If agency heads could routinely be subpoenaed to appear in agency enforcement proceedings, their ability to execute their statutory duties would be significantly impaired, and the public interest would suffer as a result.

The court of appeals correctly recognized (Pet. App. 10-11) that no compelling circumstances require Commissioner Kessler's testimony in this case. To establish a claim of selective prosecution, a defendant must show both impermissible motive and discriminatory effect. *Wayte* v. *United States*, 470 U.S. 598, 608 (1985). The courts of appeals have consistently held that defendants seeking to prove selective prosecution must demonstrate that (a) similarly situated persons who have committed the same acts have not been prosecuted and (b) their own prosecution resulted from impermissible motivations. See, *e.g.*, *United States* v. *Gutierrez*, 990 F.2d 472, 475 (9th Cir. 1993); *Owen* v. *Wainwright*, 806 F.2d 1519, 1523 (11th Cir. 1986), cert. denied, 481 U.S. 1071 (1987).

[2] The FDA informs us that it brings more than 200 civil and criminal enforcement proceedings each year.

As the court of appeals noted (Pet. App. 11), Commissioner Kessler joined the FDA only after this case had been referred to the Justice Department for prosecution, and thus he is in no position to provide first-hand testimony concerning the agency's motivations in initiating the prosecution. At most, the Commissioner could testify only in general terms about current FDA policy on the importation of AIDS-related drugs. There is no conceivable justification for requiring such a report from the head of the agency, particularly where, as here, petitioners have already obtained the testimony of other FDA officials on the only issues that Commissioner Kessler could address.

2. Petitioners contend (Pet. 8-11) that the court of appeals erred in quashing their subpoena based on a legal standard that applies only in civil cases. According to petitioners, they were entitled to Dr. Kessler's testimony under the allegedly more lenient standards applicable to criminal discovery.

Contrary to petitioners' contention, the courts have not established a different rule for determining when the testimony of high-ranking government officials will be compelled at the behest of a criminal defendant. Rather, the same rule applies in both criminal and civil cases—that high-ranking officials should not be required to testify absent particularized findings of need. See, *e.g.*, *United States* v. *Winner*, 641 F.2d at 834. Petitioner cites no authority to the contrary.[3]

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[3] The cases on which petitioners rely (Pet. 9) are inapposite, because none of them involves a subpoena for the testimony of a high-ranking government official.

Petitioners' contention also ignores established case law holding that discovery with regard to claims of selective prosecution is permitted only when a defendant first produces evidence tending to show both discriminatory impact and improper motivation. As the Second Circuit held in the leading case of *United States* v. *Berrios*, 501 F.2d 1207, 1211-1212 (1974), the courts will "first require some evidence tending to show the existence of the essential elements of the defense and that the documents in the government's possession would indeed be probative of these elements." See also *United States* v. *Heidecke*, 900 F.2d 1155, 1159 (7th Cir. 1990); *United States* v. *Penagaricano-Soler*, 911 F.2d 833, 837 (1st Cir. 1990); *United States* v. *Peete*, 919 F.2d 1168, 1176 (6th Cir. 1990); *United States* v. *Murdock*, 548 F.2d 599, 600 (5th Cir. 1977). After obtaining extensive discovery and the testimony of several FDA officials, petitioners cannot show evidence tending to establish the elements of their selective prosecution claim, much less evidence that would require testimony from Commissioner Kessler. Accordingly, petitioners' claims do not warrant further review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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OCTOBER 1993